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TOXICOLOGY DEPARTMENT

P.O. BOX 12014, 2 T.W. ALEXANDER DRIVE RESEARCH TRIANGLE PARK, NC 27709 (919) 549-2000 TELEFAX (919) 549-8525 INTERNATIONAL TELEX NUMBER 4999378—ANSWERBACK APC RTP

September 14, 1992



CERTIFIED MAIL 92 SEP 21 AM 7: 55 RETURN RECEIPT REQUESTED P 713 002 904

DOMEST RECEIPT OF

BEHQ -92 - 12193 88 92 00 10419 INIT

Document Processing Center (TS-790)
Office of Toxic Substances
US Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance Audit Program

CAP ID No.: 8ECAP - 0004

Dear Sir/Madam:

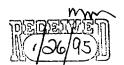
On behalf of Rhône-Poulenc Inc. (RPI, CN 5266, Princeton, NJ 08543-5266) and its subsidiary Rhône-Poulenc Ag Company (RPAC), the attached study report is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program and the Agreement for a TSCA Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA.

The enclosed study report provides information on chlormephos. The CAS number assigned to this compound is 24934-91-6. The CAS name is S-(chloromethyl) O,O-diethyl phosphorodithioate. This chemical was manufactured in Europe and imported for pesticide research and development. To our knowledge, a pesticide application on this chemical has never been submitted to EPA under the Federal Insecticide, Fungicide, and Rodenticide Act.

No claims of confidentiality are made for this submission. The title of the enclosed report is "The Effects of Chlormephos Technical on the Eye Mucosa of New Zealand Albino Rabbits". The following is a summary of the adverse effects observed in this study.

This study is being submitted under Section 8(e) because instillation of 0.1 ml of the material into rabbits' eyes resulted in severe systemic toxicity and the death of 7 out of 9 animals. Within 2 hours of instillation, one rabbit in Group I (no wash) was dead and all other Group I rabbits were severely depressed. By 7 hours post administration, four more rabbits from Group I and one animal from Group II (the one minute wash group) were dead. One additional rabbit from Group II was found dead the morning of Day 1 post administration. The two surviving animals (one from each group) were prostrate on Day 1 and were then sacrificed.

One previous TSCA Section 8(e) notice was submitted on this chemical on August 31, 1978. We do not have an EPA Document Control Number for this submission in our records. In addition, approximately 15 submissions will be made on chlormephos under the CAP.



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(2)

In total, RPI is submitting three copies of the enclosed report and this cover letter: an original and two copies.

Further questions regarding this submission may be directed to the undersigned at 919-549-2222.

Sincerely,

Glenn S. Simon, PhD, DABT

Director of Toxicology

THE EFFECTS OF CHLORMEPHOS TECHNICAL ON THE EYE MUCOSA OF NEW ZEALAND ALBINO RABBITS

Study No. BCE0778

Report No. SEH 78:40

Toxicology-Pathology Laboratory Rhodia Inc. Ashland, Ohio 44805

August 24, 1978

THE EFFECTS OF CHLORMEPHOS TECHNICAL ON THE EYE MUCOSA OF NEW ZEALAND ALBINO RABBITS

TABLE OF CONTENTS

						Page
Summary	•	•	•	•	•	1
Experimental						
Results and Discussion						
Table 1 Grades for Ocular Reactions	•	•	•	•	•	5-6



HESS & CLARK DIVISION ASHLAND, OHIO 44805



Author: S. E. Hastings, B.S.

SEH 78:40 Report No.

August 24, 1978 Date:

Page:

Primary Eye Irritation, Chlormephos Technical

Pages 74-78 Book No. 5403

5407 Pages 23-28

Dates: 6-6-78 to 6-7-78 Study No. BCE0778

TITLE

The Effects of Chlormephos Technical on the Eye Mucosa of New Zealand Albino Rabbits

PURPOSE

To determine if the instillation of Chlormephos Technical in the eyes of rabbits has any irritating effect according to the EPA proposed guidelines of April, 1978; 162.81-4.

LOCATION

The study was conducted at the Rhodia Inc., Toxicology-Pathology facility on the Hess & Clark Research Farm in Ashland, Ohio.

SPONSOR

The study was sponsored by Rhodia Inc., Agricultural Division, Monmouth Junction, New Jersey.

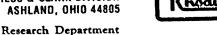
SUMMARY

A 0.1 ml aliquot of Chlormephos Technical instilled into the right eye of 9 adult female rabbits caused the death of 7 of the rabbits. Six of the rabbits died on day 0 and 1 rabbit was found dead on day 1. The 2 surviving rabbits were sacrificed on day 1 post administration. Of the six rabbits dying on day 0, 1 was from Group II, the one minute wash group. The rabbit that was found dead on day 1 was also from Group II.

The extreme systemic toxicity following ocular administration of Chlormephos Technical, made it impractical to determine the effect of Chlormephos Technical on the eye mucosa of rabbits.



HESS & CLARK DIVISION ASHLAND, OHIO 44805





Author: S. E. Hastings, B.S. Report No. SEH 78:40

Page:

EXPERIMENTAL

MATERIALS AND METHODS

ANIMALS

Nine adult female New Zealand albino rabbits were purchased from Davidson's Mill Farm, Jamesburg, New Jersey and weighed between 2 and 3 kg at the start of the study.

HOUS ING

Quarantine - the rabbits were held in a quarantine room for a 2 week acclimation period. The rabbits were housed 3 per sex in large wire bottom animal cages, 71 x 86 x 71 cm. The rabbits received food and water ad libitum. The feeders, waterers and cage floor racks were cleaned once per week. waste pans were flushed at least once per day and more often if required. The quarantine and test rooms were temperature (69°F ± 1°), humidity (50%) and light (14 hours on, 10 hours off) controlled.

During the quarantine-acclimation period, the rabbits were examined by a veterinarian with respect to their state of health and suitability as test animals. The eyes of the test rabbits were examined using the fluorescein dye procedure and only those rabbits without defects or irritation were used. The quarantine and test rooms were maintained so as to exclude materials that might produce eye irritation. Conventional disease control was practiced during the quarantine-acclimation and study period.

Study Room - at the end of the quarantine period, the rabbits were moved into the test room and transferred into individual suspended wire bottom rabbit cages, 46 x 51 x 33 cm. The rabbits received food and water ad libitum. A liquid litter from Pharmacal, Westport, Conn., was used in the litter pans and was changed twice weekly.

DIET

For the first 5 days of the acclimation period the rabbits were treated prophylactically with Pfizer's Neo-Terramycin soluble powder (5g/gallon) in the drinking water to prevent illness from diet change.



HESS & CLARK DIVISION ASHLAND, OHIO 44805

Research Department



Author: S. E. Hastings, B.S. Report No. SEH 78:40

3 Page:

The rabbits were maintained on a diet of tap water and Wayne Rabbit Ration manufactured by Allied Mills, Fort Wayne, Indiana and containing 2% crude fat, 17% crude protein and 15% crude fiber and 0.025% of sulfaquinoxaline.

IDENTIFICATION

The rabbits were identified by a number tattooed in the right ear, 151-156, Group I; 251-253, Group II. An identifying tag was placed on each rabbit's cage indicating the rabbit's number, the study number and whether it was in Group I or II.

TEST SUBSTANCE

The test substance was Chlormephos Technical P.O.X. 150, Batch No. DA 109, a clear liquid organophosphate insecticide supplied by Rhodia Inc., Agricultural Division, Monmouth Junction, New Jersey, shipped from Rhodia Inc., Agricultural Division, St. Joseph, Mo., and received April 26, 1978, with a GLC analysis of 94.4%. A density of 1 gm/ml was assumed. Each ml would contain 944 mg of Chlormephos Technical.

TEST PROCEDURE

A 0.1 ml aliquot of the test substance was placed on the everted lower lid of the right eye of 9 rabbits. The upper and lower lids were gently held together for 20-30 seconds then released. The left eye remained untreated and served as a control. The treated eyes of 6 rabbits (Group I) remained unwashed. The remaining 3 rabbits had the treated eye flushed for 1 minute with lukewarm water starting no sooner than 20-30 seconds after instillation. These rabbits were designated as Group II.

RECORDS MAINTAINED

A study record book was maintained and included the clinical observations on the rabbits for the 24 hours of the study.

STORAGE OF DATA

All raw data generated during this study and the final report are stored in the archives of Rhodia Inc., Toxicology-Pathology facility in Ashland, Ohio.



HESS & CLARK DIVISION ASHLAND, OHIO 44805





Author: S. E. Hastings, B.S. Report No. SEH 78:40
Page: 4

RESULTS AND DISCUSSION

Within 2 hours of administering 0.1 ml of Chlormephos Technical in the test eyes of 9 rabbits, one rabbit in Group I (no wash) was dead and all the other Group I rabbits were severely depressed. By 7 hours post administration, 4 more rabbits from Group I, and 1 from Group II (the one minute wash group) were dead. One rabbit from Group II was found dead the morning of day 1 post administration. The 2 survivors (one in Group I and one in Group II) were prostrate on day 1 and were then sacrificed.

Due to the extreme systemic toxicity of Chlormephos Technical, it was not possible to determine the effect of this material on the eye mucosa of rabbits.

S. E. Hastings, B.S.

Toxicologist

John G. Page, Ph. D.

Manager, Toxicology-Pathology

Rhodia Inc.

J. C. Winbigler, B.S., M.T.

Toxicologist

E. M. Kiggins, Ph.D.

Director of Research

& Product Development

Table 1

Scale for Scoring Ocular Lesions

(1)	Cornea							
	(A) Opacity-degree of density (area most dense taken for reading) No opacity Scattered or diffuse area, details of iris clearly visible Easily discernible translucent areas, details of iris slightly obscured Opalescent areas, no details of iris visible, size of pupil barely discernible Opaque, iris invisible	0 1 2 3 4						
	(B) Area of cornea involved One quarter (or less) but not zero Greater than one quarter, but less than half Greater than half, but less than three quarters Greater than three quarters, up to whole area Score (AxB) x 5 Total Maximum = 80	1 2 3 4						
(2)	<u>Iris</u>							
	Normal Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combination of any thereof) iris still reacting to light (sluggish reaction is positive) No reaction to light, hemorrhage, gross destruction (any or all of these) Score (C) x 5 Total Maximum = 10	0 1 2						
(3)	Conjunctivae (D) Redness (refers to palpebral and bulbar conjunctivae excluding cornea and iris) Vessels normal Vessels definitely injected above normal More diffuse, deeper crimson red, individual vessels not easily discernible Diffuse beefy red	0 1 2 3						
	(E) Chemosis No swelling Any swelling above normal (includes nictitating membrane) Obvious swelling with partial eversion of lids Swelling with lids about half closed Swelling with lids about half closed to completely closed	1 2 3						

Table 1 (Cont'd)

Scale for Scoring Ocular Lesions

(F)	Discharge	. 0
	No discharge	
	Any amount different from normal (does not include small)	1
	Discharge with moistening of the 11ds and mails just	. 2
•		٠, -
• *	Discharge with moistening of the lids and hairs, and	3
Scor	considerable area around the eye (D+E+F) x 2 Total Maximum = 20	• •

NOTE: The maximum total score is the sum of all scores obtained for the cornea, iris and conjunctivae.

Front Sheet

Chemical Chlormephos Technical BCE0778 Study No. Purity _ 94.4% Project No. Eye Irritation Animal Rabbit Sponsor Agricultural Division, Rhodia Inc. M No. Start Date 6-6-78 Start Weight 7 days Duration Finish Date 6-13-78 F 2-3 kg Study Director S. E. Hastings Route Eye Study Personnel HH

		Treatment		
Animal No.				
151-156	No wash	Group I		
251-253	One minute wash	Group II		

Assays or Special Procedures

- 1. Eye examination prior to treatment
- Eyes examined and scored 24, 48 and 72 hours and 4 and 7 days post treatment

Special Handling

Chlormephos Technical should be handled with care. Avoid skin and eye contact, use gloves. In case of accidental contact, immediately wash affected areas with large volumes of water and then report the incident to the study director.



HESS & CLARK DIVISION ASHLAND, OHIO 44805





PROTOCOL

TITLE

Primary Eye Irritation in Rabbits with Chlormephos, Technical

PURPOSE

To determine if the instillation of Chlormephos, Technical in the eyes of rabbits has any irritating effect according to the EPA proposed guidelines of April, 1978; 162.81-4.

LOCATION

The study will be conducted at the Rhodia, Inc., Toxicology-Pathology facility on the Hess & Clark Research Farm in Ashland, Ohio.

SPONSOR

The study is sponsored by Rhodia, Inc., Agricultural Division, Mommouth Junction, New Jersey.

ANIMALS

Nine female New Zealand white rabbits will be purchased from Davidson's Mill Farm, Jamesburg, New Jersey and will weigh between 2 to 3 kg at the start of the study.

HOUSING

Quarantine - the rabbits will be held in a quarantine room for a 1 to 2 week acclimation period depending on the age and weight of the rabbits. The rabbits will be housed 3 per sex in large wire bottom animal cages, 71 x 86 x 71 cm. The rabbits will receive feed and water ad libitum. The feeders, waterers and cage floor racks will be cleaned once per week. The waste pans will be flushed at least once per day and more often if required. The quarantine and test room will be temperature $(69^{\circ} \text{F} \pm 1^{\circ})$, humidity (50%) and light (14 hours on, 10 hours off) controlled.

When the newly arrived rabbits are distributed into the gang cages, care will be taken to put as many box mates as possible in the same gang cage.

During the quarantine-acclimation period, the rabbits will be examined by a veterinarian with respect to their state of health and suitability as test animals.

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HESS & CLARK DIVISION ASHLAND, OHIO 44805



Research Department

The eyes of the test rabbits will be examined using the fluorescein dye procedure and only those rabbits without defects or irritation will be used. The quarantine and test room will be maintained so as to exclude materials that might produce eye irritation. Conventional disease control will be practiced during the quarantine-acclimation and study period.

Study Room - At the end of the quarantine period, the rabbits will be moved into the test room and transferred into individual suspended wire bottom rabbit cages, 46 x 51 x 33 cm. The rabbits will receive food and water ad libitum. The feeders, waterers and cage floor racks will be cleaned once per week. A liquid litter from Pharmacal, Westport, Conn., will be used in the litter pans and will be changed twice weekly.

DIET

For the first 5 days of the acclimation period the rabbits will be treated prophylacticly with Pfizer's Neo-Terramycin soluble powder (5 g/gallon) in the drinking water to prevent illness from diet change.

The rabbits will be maintained on a diet of tap water and Wayne Rabbit Ration manufactured by Allied Mills, Fort Wayne, Indiana and containing 2% crude fat, 17% crude protein and 15% crude fiber and 0.025% of sulfaquinoxaline.

IDENTIFICATION

The rabbits will be identified by a number tattooed in the right ear, 151-156, Group I; 251-253, Group II. An identifying tag will be placed on each rabbit's cage indicating the rabbit's number, the study number and whether it is in Group I or II.

TEST SUBSTANCE

The test substance will be Chlormephos Technical P.O.X. 150, Batch No. DA 109, a clear liquid organophosphate insecticide supplied by Rhodia Inc., Agricultural Division, Monmouth Jct., New Jersey, shipped from Rhodia Inc., Agricultural Division, St. Joseph, Mo., and received April 26, 1978 with a GLC analysis of 94.4%.

Warning: Handle with care, avoid skin and eye contact, use gloves. In case of accidental contact, immediately wash all affected areas with large volumes of water and report the incident to the study director.



HESS & CLARK DIVISION ASHLAND, OHIO 44805



Research Department

TEST PROCEDURE

A 50 mg or 0.1 ml aliquot of the test substance will be placed on the everted lower lid of the right eye of 9 rabbits. The upper and lower lids will be gently held together for 20-30 seconds then released. left eye will remain untreated and will serve as a control. The treated eyes of 6 rabbits (Group I) will remain unwashed. The remaining 3 rabbits will have the treated eye flushed for 1 minute with lukewarm water starting no sooner than 20-30 seconds after instillation. These rabbits will be designated as Group II.

OBSERVATIONS

The eyes will be examined by the fluorescein dye technique and the grade of ocular reaction recorded at 24, 48, 72 hours and 4 and 7 days postinstillation and daily thereafter, so long as injury persists (up to 14 days). The eyes will be graded and the irritation scores determined by the Draize procedure in accordance with Tables 1 and 2.

RECORDS TO BE MAINTAINED

A study record book will be maintained according to Manual #19 in the Standard Operating Procedures and in addition the following records will be maintained:

Group I observation sheets

Group II observation sheets

Group I irritation scores

Group II irritation scores

DATA ANALYSIS AND FINAL REPORT

A final report will be issued. The data will be tabulated and will include the individual primary eye irritation score at 24, 48 and 72 hours and 4 and 7 days for each rabbit and the averages and range for each test group. Any serious lesions of the eye will be described.

STORAGE OF DATA

All raw data generated during this study and the final report will be stored in the archives of Rhodia, Inc., Toxicology-Pathology facility in Ashland, Ohio.

S. E. Hastings, 🎉 S.

Study Director

ATIMAR! Approved by:

John G. Page, Ph.D.

Manager, Toxicology-Pathology

Rhodia, Inc.

Approved by:

E. M. Kiggins, Ph.D. Director of Research & Product Development

Table 1

Scale for Scoring Ocular Lesions

(1)	Cornea	•
•	(A) Opacity-degree of density (area most dense taken for reading) No opacity	0
	tice avea details of this clearly vacant	1
	Easily discernible translucent areas, details of iris slightly obscured	2
,	slightly obscured Opalescent areas, no details of iris visible, size of pupil barely discernible Opaque, iris invisible	3 4
! >		_
	One quarter (or less) but not zero Greater than one quarter, but less than half Greater than half, but less than three quarters Greater than three quarters, up to whole area Score (AxB) x 5 Total Maximum = 80	1 2 3 4
(2)	<u>Tris</u>	
\-,	(C) Values	0
	Normal Folds above normal, congestion, swelling, circumcorneal folds above normal, congestion, swelling, circumcorneal	-
•	thereof) iris still reacting to light (blugger)	1
	reaction is positive) No reaction to light, hemorrhage, gross destruction (any or all of these)	2
	Score (C) x 5 Total Maximum = 10	
(3)	Conjunctivae	
•	(D) Redness (refers to palpebral and bulbar conjunctivae	
	excluding cornea and iris) Vessels normal	0
	· · · · · · · · · · · · · · · · · · ·	1
	Vessels definitely injected above normal vessels not More diffuse, deeper crimson red, individual vessels not easily discernible Diffuse beefy red	3
	(E) Chemosis	٠.
	No swelling Any swelling above normal (includes nictitating membrane)	1
	Alastana arrallino With Dartial everbasis	2
	Swelling with lids about half closed Swelling with lids about half closed to completely closed	2

Table 1 (Cont'd)

Scale for Scoring Ocular Lesions

(F)	Discharge	. 0
	No discharge Any amount different from normal (does not include small amounts observed in inner canthus of normal animals)	1
	Discharge with moistening of the flus and hazza	. 2
See	adjacent to lids Discharge with moistening of the lids and hairs, and considerable area around the eye (D+E+F) x 2 Total Maximum = 20	3

NOTE: The maximum total score is the sum of all scores obtained for the cornea, iris and conjunctivae.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

Glenn S. Simon, Ph.D., DABT
Director of Toxicology
Rhône-Poulenc
P.O. Box 12014
2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MAR 3 0 1995

PA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

all TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 1110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Risk Analysis Branch

Enclosure

12193A

Triage of 8(e) Submissions

Date sent to triage:		MAY 10 1		I-CAP	CAP	
Submission number:	121934	<u> </u>	TSC	A Inventory:	Y 1	
Study type (circle app	propriate):					
Group 1 - Dick Cleme	ents (1 copy tota	ıl)				
ECO	AQUATO					
Group 2 - Ernie Falke	e (1 copy total)					
ATOX	SBTOX	SEN	w/NEUR			
Group 3 - Elizabeth	Margosches (1 c	opy each)				
STOX	стох	EPI	RTOX	GTOX		
STOX/ONCO	CTOX/ONCO	IMMUNO	СҮТО	NEUR		
Other (FATE, EXPO,	MET, etc.):					
Notes:						
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SEQ. A INFORMATION REQUESTED: FLWP DATE: 6501 NO INFO REQUESTED 6502 INFO REQUESTED (TECH) 6503 INFO REQUESTED (VOL ACTIONS) 6504 INFO REQUESTED (REPORTING RATIONALE) DISPOSITION: 6428 REFER TO CHEMICAL SCREENING 6438 CAP NOTICE	OTS DATE: OF 21/93 CSRAD DATE: O1/34/95 S-(Chloromethyl) 0,0-duthyl 11	F E C	ONGOING REVIEW YES (DROPREFER) NO (CONTINUE) MED HIGH	•
CECATS DATA: C9 Q2 - 12/93 SEQ. 3 SUBMITTER NAME: Rhorz - Poulenc	SUB DATE: OQ 14 (92 OT CHEMICAL NAME: Chlor mephos Chlor poporodimate	INFORMATION TYPE: 0201 ONCO (HUMAN) 0202 ONCO (ANIMAL) 0203 CELL TRANS (IN VITRO) 0204 MUTA (IN VITRO) 0205 MUTA (IN VITRO) 0206 MUTA (IN VITRO) 0206 MUTA (IN VIVO) 0206 MEDRO/TERATO (HUMAN) 0207 REPRO/TERATO (ANIMAL) 0210 ACUTE TOX. (HUMAN) 0211 CHR. TOX. (HUMAN) 0212 ACUTE TOX. (HUMAN) 0213 SUB ACUTE TOX (ANIMAL) 0214 SUB CHRONIC TOX (ANIMAL) 0215 CHRONIC TO	S S	

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0 0 0 0 0 0 0 0 0 0 0 0 0 > <ID NUMBER> 8(e)-12193A

> <TOX CONCERN>

> <COMMENT>

EYE KILL IS HIGH CONCERN IN RABBITS. 7 OUT OF 9 ANIMALS DIED WHEN EXPOSED TO 0.1 ML OF TEST MATERIAL. 6 EYES REMAINED UNWASHED WHILE THE 3 REMAINING EYES WERE FLUSHED AFTER ONE MINUTE. DUE TO EXTREME SYSTEMIC TOXICITY FOLLOWING APPLICATION THE EFFECTS ON THE EYES WERE NOT DETERMINED. CLINICAL OBSERVATIONS BEFORE DEATH INCLUDED SEVERE DEPRESSION AND PROSTRATION.

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